4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0850]

Gilead Sciences, Inc.; Withdrawal of Approval of Indications for Relapsed Follicular Lymphoma and Relapsed Small Lymphocytic Lymphoma for ZYDELIG (Idelalisib) Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that it is withdrawing approval of the indications for relapsed follicular lymphoma and relapsed small lymphocytic lymphoma for ZYDELIG (idelalisib) Tablets, approved under new drug application (NDA) 205858, held by Gilead Sciences, Inc., 333 Lakeside Dr., Foster City, CA 94404 (Gilead). Gilead voluntarily requested that the Agency withdraw approval of these indications and waived its opportunity for a hearing.

DATES: Approval is withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137, Kimberly.Lehrfeld@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: On July 23, 2014, FDA approved NDA 205858 for ZYDELIG (idelalisib) Tablets for the treatment of patients with relapsed follicular B-cell non-Hodgkin lymphoma in patients who have received at least two prior systemic therapies (the follicular lymphoma indication). On that same day, FDA also approved NDA 205858 for ZYDELIG (idelalisib) Tablets for the treatment of patients with relapsed small lymphocytic lymphoma in patients who have received at least two prior systemic therapies (the SLL indication). FDA approved both the follicular lymphoma indication and the SLL indication

under the Agency's accelerated approval regulations, 21 CFR part 314, subpart H. As a condition of accelerated approval of ZYDELIG (idelalisib) Tablets for the follicular lymphoma indication and the SLL indication, the applicant was required to conduct postmarketing trials to verify the clinical benefit of idelalisib for the follicular lymphoma and SLL indications.

On November 22, 2021, FDA met with Gilead to discuss the status of ZYDELIG (idelalisib) Tablet's accelerated approval for the follicular lymphoma indication and the SLL indication, including the continued need for postmarketing trials intended to verify clinical benefit in follicular lymphoma and small lymphocytic lymphoma. FDA raised withdrawal of approval during this discussion, explaining its intent to consult the Oncologic Drugs Advisory Committee (ODAC) on whether FDA should pursue withdrawal of the follicular lymphoma indication and the SLL indication. Subsequently, on December 17, 2021, following further communication with Gilead, FDA advised Gilead that voluntary withdrawal of approval for these indications would be appropriate under § 314.150(d) (21 CFR 314.150(d)). On January 10, 2022, Gilead submitted a letter requesting withdrawal of the follicular lymphoma indication and the SLL indication for ZYDELIG (idelalisib) Tablets and waiving its opportunity for a hearing. Gilead subsequently clarified, on February 23, 2022, that they were requesting the Agency withdraw approval of the follicular lymphoma indication and the SLL indication pursuant to § 314.150(d).

Therefore, under § 314.150(d), approvals of the follicular lymphoma indication and the SLL indication for ZYDELIG (idelalisib) Tablets are withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Withdrawal of approval of these indications does not affect any other approved indication for ZYDELIG (idelalisib) Tablets.

Dated: May 19, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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